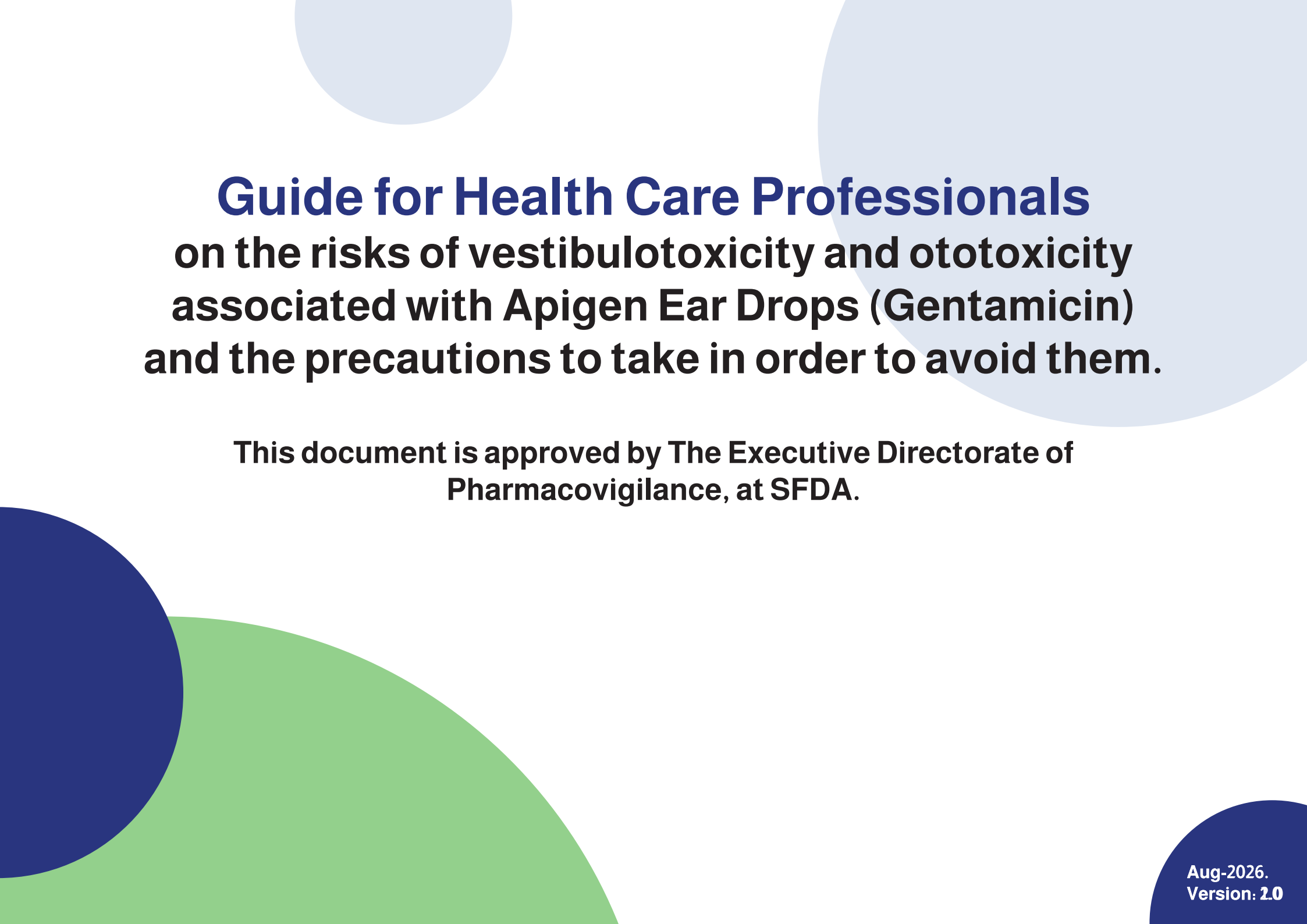




Guide for Health Care Professionals **on the risks of vestibulotoxicity and ototoxicity** **associated with Apigen Ear Drops (Gentamicin)** **and the precautions to take in order to avoid them.**

**This document is approved by The Executive Directorate of
Pharmacovigilance, at SFDA.**

Guide for Health Care Professionals

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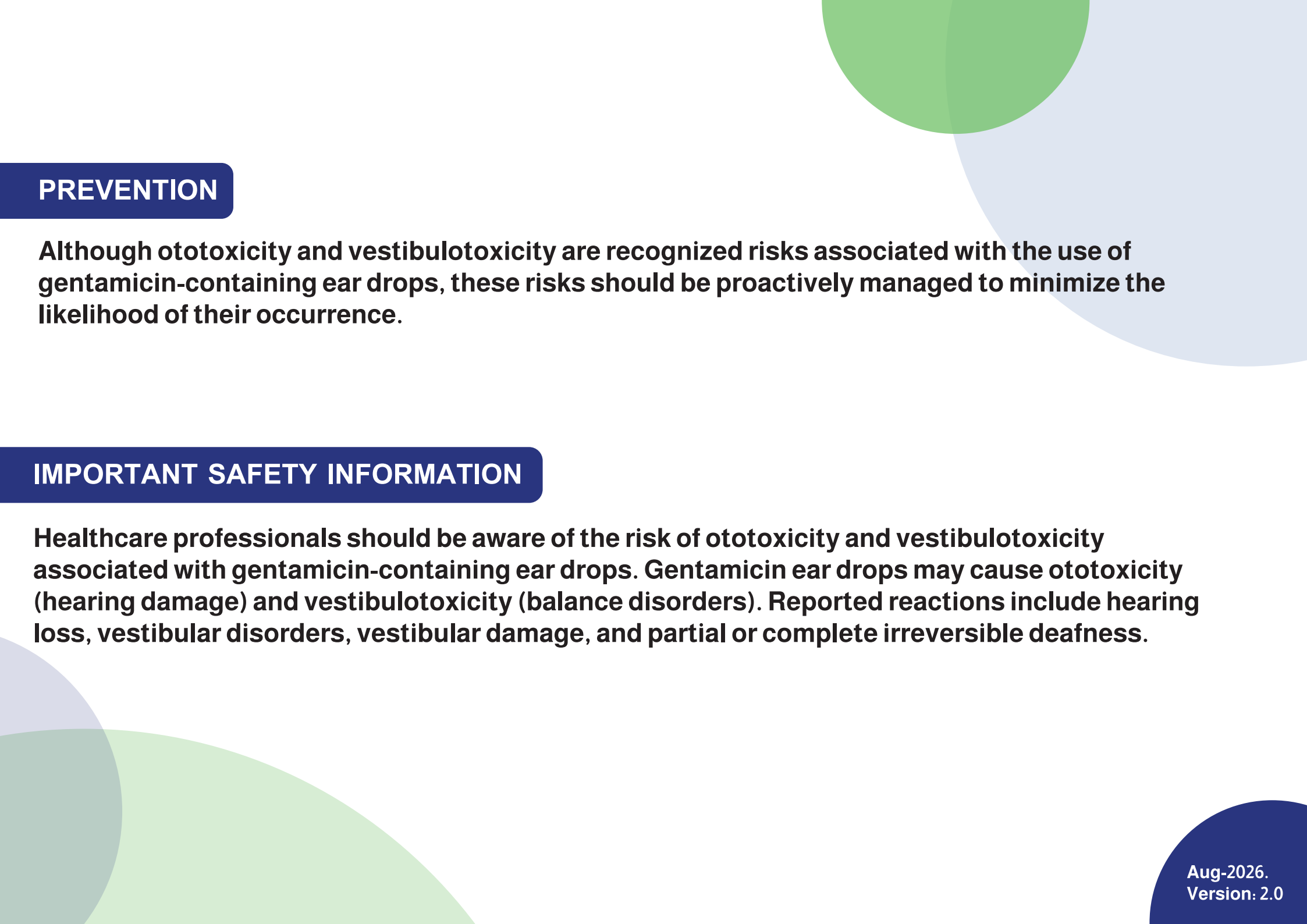
OBJECTIVE

The educational material is for ensuring the safe and effective use of the gentamicin-containing ear drops, as it provides information on appropriate patient selection, safe prescribing practices, and risk minimization measures to reduce the risk of ototoxicity and vestibulotoxicity.

Read the guide before prescribing or dispensing Apigen ear drops.

THERAPEUTIC INDICATIONS

For ear use, the product is indicated for the treatment of otitis externa.



PREVENTION

Although ototoxicity and vestibulotoxicity are recognized risks associated with the use of gentamicin-containing ear drops, these risks should be proactively managed to minimize the likelihood of their occurrence.

IMPORTANT SAFETY INFORMATION

Healthcare professionals should be aware of the risk of ototoxicity and vestibulotoxicity associated with gentamicin-containing ear drops. Gentamicin ear drops may cause ototoxicity (hearing damage) and vestibulotoxicity (balance disorders). Reported reactions include hearing loss, vestibular disorders, vestibular damage, and partial or complete irreversible deafness.

- **Ototoxicity**

Ototoxicity refers to damage affecting the auditory system and may result in impairment of hearing function. Reported adverse reactions associated with gentamicin include:

- **Hearing loss.**
- **Partial deafness.**
- **Total deafness.**
- **Irreversible auditory injury.**

The risk of ototoxicity is known to be dose-related and may be enhanced by certain patient-related factors and concomitant medical conditions.

- **Vestibulotoxicity**

Vestibulotoxicity refers to damage involving the vestibular system of the inner ear, which is responsible for maintenance of balance and spatial orientation. Reported vestibular adverse reactions associated with gentamicin include:

- **Vestibular damage.**
- **Vestibular disorders.**

Balance disturbances requiring clinical evaluation and monitoring.

Healthcare professionals should consider vestibular toxicity when evaluating patients who develop new vestibular symptoms during treatment.

- **Patients at Increased Risk:**

Particular caution should be exercised in:

- **Elderly patients.**
- **Patients with renal impairment.**
- **Patients with hepatic impairment.**
- **Patients receiving concomitant nephrotoxic or ototoxic medications.**

These factors may increase susceptibility to gentamicin-associated toxicity and should be considered before treatment initiation.

KEY SAFETY MESSAGES

Healthcare professionals should be aware of the following key safety recommendations when prescribing gentamicin-containing ear drops:

- **A confirmed intact tympanic membrane. Consider alternative treatment options if there is any suspicion of tympanic membrane perforation or damage.**
- **Consider culture and antimicrobial susceptibility testing, where clinically appropriate, to support the selection of gentamicin based on the susceptibility of the causative microorganism.**
- **Review patient-specific risk factors.**
- **Assess for renal impairment.**
- **Assess for hepatic impairment.**
- **Use particular caution in elderly patients.**
- **Review concomitant medications for ototoxic or nephrotoxic potential.**

MANAGEMENT OF THE RISKS

- **Avoid unnecessary prolonged treatment.**
- **Ototoxicity effect is dose-related and is enhanced by renal and/or hepatic impairment and is more likely in the elderly.**
- **Counsel patients regarding the signs and symptoms of ototoxicity and vestibulotoxicity.**
- **Discontinue treatment if patients develop auditory (hearing loss, tinnitus) or vestibular (vertigo or disequilibrium) symptoms.**
- **Avoid concurrent use with other potentially ototoxic medicinal products, including potent diuretics such as ethacrynic acid and frusemide, unless considered essential by the physician.**

ADVERSE REACTION REPORTING

- **For full information on all possible adverse events please see the SPC.**
- **Adverse reactions should also be reported to Amman Pharmaceutical Industries via the Company contact point that is provided below.**



Amman Pharmaceutical Industries
شركة عمان للصناعات الدوائية

All cases of ototoxicity and vestibulotoxicity with Gentamicin ear drops should be reported to:

The National Pharmacovigilance Centre (NPC) - Saudi Food and Drug Authority (SFDA):



SFDA call center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa/>

Report to SFDA

And/or

Amman Pharmaceutical Industries Pharmacovigilance office (Riyadh, Saudi Arabia) at:



E-mail:

Ghadah.Alotaibi@ammanpharma.com

Mobile: +966507917875

Report to Amman
Pharmaceutical
Industries

***To acquire an additional copy of this guide, please contact the provided information directly.**

References:

1. Summary of Product Characteristics and Package Leaflet for Apigen Eye Ear Drops® (Current applicable versions). Amman Pharmaceutical Industries.
2. Position Statement: Use of Topical Antibiotic Drops - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
3. Position Statement: Ototoxicity - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
4. Rosenfeld RM, Schwartz SR, Cannon CR, Roland PS, Simon GR, Kumar KA, Huang WW, Haskell HW, Robertson PJ. Clinical practice guideline: acute otitis externa. Otolaryngol Head Neck Surg. 2014 Feb;150(1 Suppl):S1-S24. doi: 10.1177/0194599813517083. Erratum in: Otolaryngol Head Neck Surg. 2014 Mar;150(3):504. Erratum in: Otolaryngol Head Neck Surg. 2014 Mar;150(3):504. doi: 10.1177/0194599814524717. PMID: 24491310.